

Remarks

Claims 1-15 are pending in the current patent application. Before addressing the office action on the merits. Applicant would like to point out an error in the Office Action Summary. The box "8" in the Disposition of Claims is marked; however, the office action does not state any restrictions or election requirements. Instead, the office action provides rejections of the claims.

The specification was amended to correct an inadvertent and obvious error in paragraph [0089] on page 21. The third line from the bottom was amended to delete the term "not" as illustrated below.

"hGH liquid formulations tested in this Example, in which PEG polymer was ~~not~~ present. It is"

Clearly, this is a typographical error as Example 7 does refer to hGH formulations containing PEG. Therefore, the term "not" should be deleted.

Claims 1 and 11 have been amended to make the presence of methionine in the formulation a limitation and not an optional excipient.

Claims 7 and 11 were amended to recite a preferred concentration of the polymer stabilizer. Basis for this amendment can be found through out the Examples, in particular, Example 3 Table III, Samples 5-8 on page 17. Applicants reserve the right to file a continuation application to acquire the broader claims.

Claims 3 and 13 was amended to provide proper antecedent basis to the term "recombinant form of human growth hormone".

Claim 15 was amended to delete the term "and/or" and rewrite the claim to take into account that any or all of the three criteria may be met in accordance with the claim. No new matter has been added to the claim.

Claim Objection

Claim 1 was objected to because of the following informality: "excipient" in line 4. Claims 1 and 11 have been amended to correct the error.

§112 Rejections

I. Claims 7, 11-15 were rejected under 35 USC §112, 1st paragraph for lack of enablement for formulations comprising 70% to 20% polymer stabilizer.

Although Applicants do not agree, Claims 7 and 11 have been amended to recite a preferred concentration of the polymer stabilizer to expedite the application to allowance. Applicants reserve the right to file a continuation application to acquire the broader claims. Basis for this amendment can be found in Example 3 Table III, Samples 5-8 on page 17.

Sample 5-7 recite 1% PEG and Sample 8 recites 0.25% PEG. Examiner acknowledged that the specification was enabling for a formulation comprising 1% of the polymer stabilizer. Applicants respectfully submit that Sample 8 provides adequate support for 0.25% of the polymer stabilizer as well. Since 12-15 are dependent from Claim 11, the amendment of Claim 11 renders the rejection moot for these claims as well.

II. Claims 1-15 were rejected under 35 USC §112, 2nd paragraph as being indefinite.

(a) Examiner asserts the phrase “optionally further comprising” in Claim 1, line 3 and Claim 10, line 5 renders the claims indefinite.

Applicants have amended both Claims 1 and 10 to remove the language “further comprising” and make it clear that the listed excipients are optional thus rendering the rejection moot.

(b) Examiner asserts that Claim 2 lacks antecedent basis for the term “human growth hormone” in line 1.

Applicants have amended Claim 1 to include the term “human” thus providing the proper antecedent basis in Claim 2.

(c) Examiner asserts that Claim 13 recites the acronym “hGH” which lacks antecedent basis.

Applicants have amended Claim 13 to replace “hGH” with “the recombinant form of human growth hormone” thus providing proper antecedent basis to Claim 11.

(d) Examiner asserts that Claim 15 lacks proper antecedent basis for the term “storage”.

Applicants have amended Claim 15 to provide proper antecedent basis to Claim 14 thus rendering the rejection moot.

§102 Rejections

I. Claims 1-6 and 9-10 were rejected under 35 USC §102(b) as being anticipated by WO 97/29767 (McNamara et al., published on 21 August 1997).

In order for a reference to be anticipatory, it is well established that each and every key element of the claim must be present in the reference. Applicants have amended Claim 1 to include the limitation of “methionine” in the formulation. McNamara does not disclose the use of methionine in their preparations. Therefore, the rejection has been rendered moot.

II. Claims 1-6 were rejected under 35 USC §102(b) as being anticipated by US 2002/0077461 (Bjorn, et al., published on 20 June 2002).

As stated above, Applicants have amended Claim 1 to include the limitation of "methionine" in the formulation. Bjorn does not disclose the use of methionine in their preparations. Therefore, the rejection has been rendered moot.

Based on the amendments to the Claims and the arguments provided above, Applicants respectfully submit that Claims 1-15 are in condition for allowance.

Respectfully Submitted:

Date: February 20, 2009

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